Amendments to the Drawing

Please replace drawing sheet 1 with the attached replacement sheets FIG. 1 has been amended to show legible lines and to show every element of the claims.

Please add FIGS. 2A– 6 to the application.

The drawings are now believed to be compliant with 37 C.F.R. § § 1.83(a) and 1.121(d).

REMARKS

Claims 1 - 29 are pending in the present application. Claims 1 - 29 are rejected. Claim 17 is objected to. By the foregoing, Applicant has amended claims 1, 2 and 17.

Amendments to the Specification

As set forth above, application requests that original paragraphs 12-13, 15-17, 21, 24, 26-27 be replaced by the new paragraphs. Changes in the specification correspond to the elements shown in the amended and new drawings. No new matter has been included.

Corrected Drawings

The Examiner has required the submission of a new corrected drawing that is in compliance with 37 CFR 1.121(d) and that shows every feature of the invention specified in the claims pursuant to 37 CFR 1.83(a). An amended drawing of FIG. 1 and new drawings FIGS. 2A through 6 are submitted herewith. No new matter has been included.

Objection to Claim 17

The Examiner has objected to claim 17 because the phrase "the notification device" lacks antecedent basis. Applicant respectfully calls the Examiner's attention to line 8 of claim 17, where the phrase "activating a notification device" provides the antecedent basis for the phrase "the notification device" in line 10. Withdrawal of the objection is respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner has rejected claims 1-3, 6-8, 17-18, and 20-22 under 35 U.S.C. §102(a) as anticipated by U.S. Publication 2002/0103508 A1 to Marthur. This rejection is respectfully traversed.

Marthur teaches an external defibrillator system that is used by an attendant when he or she notices the patient having an attack. The system is activated by the attendant removing the pulse generator from the base system, or by the attendant performing another action. It is only upon activation that a signal is generated. *See* para. [0041]. The device disclosed in Marthur does not identify the need to defibrillate; instead, "[o]nce the device has been attached, the defibrillator is adapted to monitor the patient and to transmit information to the remotely located operator." The defibrillator of Marthur is integral to the system. Further, the defibrillation treatment is administered by the remote clinician rather than the local caregiver. *See* para. [0047-48]. In contrast, the present invention teaches a system that is not dependant on external activation. The patient's physiological rhythm is continuously monitored by the physiological parameter measuring device which is worn over an extended period of time by the patient. *See* para. [0013]. Signal generation is automatic. *Id.* The defibrillator of the present invention is free-standing and operated by the local caregiver. The foregoing amendments to independent claims 1 and 17 and their dependent claims clarify these points. Because Marthur fails to teach a device that is adapted for extended wear, that generates signals automatically, that allows the local caregiver to administer defibrillation treatment, Marthur fails to anticipate the independent claims of the present invention. The remaining rejected claims depend from claims 1 and 17 are likewise unanticipated by Marthur. Withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 1-3, 12, 13, 16-17 under 35 U.S.C. §102(b) as anticipated by U.S. Patent 5,593,426 to Morgan. This rejection is respectfully traversed.

Morgan, like Marthur, also teaches an external defibrillator system that is dependant on the action of the fist responding caregiver. The Morgan invention suffers from the same drawbacks as the Marthur invention. Morgan teaches that "in the event of a cardiac emergency, the first responding caregiver initiates deployment of the defibrillator." *See* col. 3, ln 66 to col. 4, ln 1. As shown in Fig. 1, Morgan's invention discloses an integrated defibrillator. In contrast, the present invention does not depend upon external deployment or activation; rather,

it is a system of continuous monitoring and automatic signal generation. The defibrillator of the present invention is free-standing and not integral to the warning system. These distinguishing features have been more clearly brought out in the independent claims 1 and 17 and their dependant claims. For the same reasons that Marthur fails to anticipate the present invention, Morgan also fails to teach every element of the invention and is not anticipatory. Withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 1-3, 9-10, 14, 17-18, 22, 24, 26, and 28 under 35 U.S.C. §102(b) as anticipated by U.S. Patent 3,724,455 to Unger. This rejection is respectfully traversed.

Although Unger discloses a portable, self contained and powered unit which monitors patients ECG waveforms continuously, responds to conditions which appear to be herald signs and is in communication with a central facility, the patent fails to teach each element of the invention and therefore does not anticipate the present invention. The Unger invention is adapted to use by multiple individuals prone to cardiac episodes. The present invention, on the other hand, is dedicated to a single patient who is located remotely from a medical setting. The Unger invention discloses a defibrillator that is operationally linked to the human experts at the central facility. *See* Unger patent, col. 4, lns 37-53. On the other hand, the present invention discloses a free-standing defibrillator not integral to the remaining warning system that is operated by the local caregiver. Furthermore, the specification of the Unger patent makes clear that the device is only suitable for short ranges of distance, i.e. those within range of a radio signal. For example, the Unger device "triggers an audio alarm in the unit which indicates to the individual that he should go to the nearest telephone and call the central facility." Col. 2, lns. 48-50. In contrast, in those embodiments of the present invention where communications with a central facility is contemplated, the communications are initiated automatically. Because Unger fails to show every element of the present invention, it does not constitute an anticipating reference and poses no obstacle to the patentability of independent claims 1 and 17, and their dependants. Withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §103 (a)

The Examiner has rejected many of the pending claims under 35 U.S.C. §103(a) as being unpatentable over a combination of the Unger patent and in view of several patents. Applicant respectfully traverses each of these rejections.

Rejection of Claims 4 and 19 Based on Unger In View of The Joo Patent

The Examiner has rejected many of the pending claims under 35 U.S.C. §103(a) as being unpatentable over Unger and in view of U.S. Pat. 6,440,082 to Joo. The Examiner opined that it would have been obvious to those skilled in the art to combine the Unger disclosure with Joo's teaching to determine the heart pulse before administering a defibrillation shock to arrive at the invention of claims 4 and 19.

However, even accepting that one skilled in the art would have known the Joo teaching to check for a heart pulse prior to defibrillation, Applicant contends that the combination of these "obvious" alternatives would not have resulted in his invention. Even if the underlying Unger device were to incorporate the Joo teaching, the result would still be distinguishable from the present invention due to the distinguishing features between the present invention and that of Unger.

Rejection of Claim 5 Based on Unger In View of The Joo and Johnson Patents

The Examiner rejects claim 5 of the application as unpatentable over Unger in view of Joo and U.S. Patent 3,511,227 to Johnson. Like the Unger-Joo combination discussed above, this combination does not result in the Applicant's invention. Further, there is nothing in Johnson to suggest or to motivate one skilled in the art to combine it with an external defibrillator system adapted for extended wear for constant monitoring of life-threatening rhythms and for notifying nearby caregivers.

Rejection of Claims 11 and 25 Based on Unger In View of Brewer and Nappholz

The Examiner rejected claims 11 and 25 as unpatentable over Unger in view of Brewer and, in the alternative, U.S. Patent 5,113,869 to Nappholz. The Examiner also took the position that Unger substantially disclosed the invention and that the use of an analog-to-digital converter is well-known to those skilled in the art as shown in both Brewer and Nappholz, both of which disclose devices that use such converters.

Applicant respectfully disagrees. Applicant first cites the distinct differences between his invention and that of Unger's. While Brewer includes the use of an analog-to-digital converter, the advantages of such use is not disclosed. The disclosure provides no suggestion that it would be advantages to also employ an analog-to-digital converter in a defibrillation system of the present invention. In Nappholz, the analog-to-digital converter is used in an *implanted* defibrillation system. The converter is but one of the elements in Nappholz used in conjunction with the implantation procedure and the amplifier that assure signal quality. Again, there is no suggestion or motivation provided to those skilled in the art to use an analog-to-digital converter and an amplifier. Indeed, Nappholz teaches away from such a combination: a basic premise of his invention is that only an implanted device can acquire electrocardiographic signals with sufficient quality and reliability to effectively detect these precursors. Col. 5, lns 23-28. There is simply no motivation to combine these references.

Rejection of Claims 15 and 29 Based on Unger In View of Nappholz

The Examiner rejected claims 15 and 29 as unpatentable over Unger in view of U.S. Pat. 5,184,615 to Nappholz on the grounds that it would have been obvious for those skilled in the art to combine the verification step in Nappholz with the invention of the Unger patent. Applicant urges that even were such a combination to occur, it would not arrive at the present invention and therefore the rejection is improper.

The '615 patent teaches the use of an antiarrhythmia pacemaker to confirm the presence of tachyarrhythmia prior to delivering a defibrillation shock. An antiarrhythmia

pacemaker is not used in the present invention. Instead, the invention relies on the human experts in the receiving center to evaluate the physiological data to confirm a malignant rhythm. Upon confirmation, an alarm is sent to notify the caregiver of the cardiac event. In contrast to the teachings of Nappholz, the defibrillator device of the present invention is not armed to deliver shock therapy upon confirmation of malignant arrhythmia. Nothing in the '615 patent teaches the reliance on human experts to confirm the presence of malignant arrhythmia, nor does it teach that a caregiver proximate to the patient should be notified upon such confirmation.

Rejection of Claim 23 Based on Unger In View of Davis

The Examiner opined that it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Unger and U.S. Pat. 5,544,661 to Davis et al. Davis teaches the step of paging the patient's primary care physician in the event of an emergency cardiac episode so that the physician could intercept the patient at the hospital.

Applicant argues that the notification system of the invention is fundamentally different from that disclosed in Davis et al. The pager notification in Davis provides a means of contacting the patient's physician in an effort to coordinate care at the hospital; however, the pager notification system of the present invention is used to alert a caregiver within the proximity to the patient to deliver immediate care. Nothing in Davis suggests using the pager system to alert a caregiver within proximity to the patient to deliver immediate care. Indeed, the Davis system is largely driven by the clinician in the central monitoring station communicating with the patient or someone proximate to the patient through the built-in cellular phone and public network. There is no suggestion which would motivate one of ordinary skill in the art to include the pager system to alert a caregiver proximate to the patient that a cardiac event is in progress.

For these reasons, Applicant urges the Examiner to remove the rejection under § 103(a) against claims 4, 5, 15, 19, 23 and 29.

Conclusion

Applicant has addressed all outstanding issues of the Office Action. Based on the Amendments and Remarks above, Applicant respectfully requests allowance of all pending claims.

Respectfully submitted,
SCHNADER HARRISON SEGAL & LEWIS LLP

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Joan T. Kluger
Reg. No. 38,940
Stephenie W. Yeung
Reg. No. 48,052
1600 Market Street, Suite 3600
Philadelphia, PA 19103
Tel: (215) 751-2357
Fax: (215) 751-2205
E-mail: jkluger@schnader.com
Attorneys for Applicants